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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/024,019

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Thomas P. Loughran JR.

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01/21/2005

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EXAMINER

LOCKARD, JON MCCLELLAND

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 01/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/024,019	Applicant(s) LOUGHRAN ET AL.	
	Examiner Jon M Lockard	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-4, 11-15, and 17, drawn to polynucleotides, vectors, host cells, and a method of recombinantly producing a polypeptide, classified in class 536, subclass 23.5, class 435, subclasses 320.1, 252.3, and 69.1, for example.
 - II. Claims 5 and 10, drawn to polypeptides, classified in class 530, subclass 350.
 - III. Claims 6, 7, and 9, in so far as they are drawn to a method for screening for an autoimmune disease by measuring sppr nucleic acid expression, classified in class 436, subclass 6.
 - IV. Claims 6, 8, and 9, in so far as they are drawn to a method for screening for an autoimmune disease by measuring sppr protein expression, classified in class 435, subclass 7.1.
 - V. Claims 18 and 19, in so far as they are drawn to a method for screening for a neurodegenerative disease by measuring sppr nucleic acid expression, classified in class 436, subclass 6.
 - VI. Claims 18 and 20, in so far as they are drawn to a method for screening for a neurodegenerative disorder by measuring sppr protein expression, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

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3. Inventions I and II are independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged.

4. The polynucleotide of **Group I** and the polypeptide of **Group II** are patentably distinct for the following reasons: polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polypeptide and polynucleotide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Furthermore, searching the inventions of **Groups I and II** together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides is not coextensive. The inventions of **Groups I and II** have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is also search burden in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide, but spoke to the gene. Searching, therefore, is not coextensive. Furthermore, a search of the nucleic acid molecules of **Group I** would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of Group I. As such, it would be burdensome to search the inventions of **Groups I and II**.

4. Inventions I and each of III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product, or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of Invention I can be used in

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methods of recombinant production of the protein, methods of treatment, or in diagnostic assays, which are all materially different methods.

5. Inventions II and each of IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Invention II can be used in a materially different process such as diagnostic or biochemical assays.

6. Inventions I and each of IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions I and each of IV and VI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions IV and VI do not recite the use or production of the polynucleotides of Inventions I.

7. Inventions II and each of III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions II and each of III and V are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions III and V do not recite the use or production of the polypeptides of Inventions II.

8. The various methods of Inventions III-VI are drawn to patentably distinct methods. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions III-VI are directed to methods that are distinct both physically and functionally, and are not required one for the other.

9. Invention III requires search and consideration of screening for an autoimmune disease by measuring sppr nucleic acid expression, which is not required by any of the other Inventions. Invention IV requires search and consideration of screening for an autoimmune disease by measuring sppr protein expression, which is not required by any of the other Inventions. Invention V requires search and consideration of screening for a neurodegenerative disease by measuring sppr nucleic acid expression, which is not required by any of the other Inventions. Invention VI requires search and consideration of screening for a neurodegenerative disease by measuring sppr protein expression, which is not required by any of the other Inventions. Invention VIII requires search and consideration of treatment by administering a polynucleotide, which is not required by any of the other Inventions.

10. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-

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patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Further Restriction Within Groups I-VI

11. For whatever group is elected, further restriction within the elected group is required, as follows.

Group I, III, and V

12. If group I, III, or V is elected, Applicants must further elect *one* nucleic acid selected from SEQ ID NO:4, SEQ ID NO:9, or SEQ ID NO:13.

Group II, IV, and VI

13. If group II, IV, or VI is elected, Applicants must further elect *one* polypeptide selected from SEQ ID NO:3, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, or SEQ ID NO:14.

14. Although classifications for the nucleic acids and proteins are overlapping, each represents a patentably distinct product, having different chromosomal locations and sequences for the nucleic acids of group I and different amino acid sequences, structures and activities for the polypeptides of group II, and each would require separate sequence searches. Furthermore, searching the 3 different inventions of each of **Groups I, III and V** and 5 different inventions of each of **Groups II, IV, and VI** would impose a serious search burden since a search of one of the polynucleotides of **Group I, III, and V**, for example, would not be used to determine the

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patentability of any of the other 2 polynucleotides, and vice-versa. Lastly, the methods of using the nucleic acids and proteins are also therefore patentably distinct.

Applicants are advised that this is not a species election.

15. The Examiner has required restriction between product and method claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn method claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Method claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

16. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined method claims will be withdrawn, and the rejoined method claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and method claims may be maintained. Withdrawn method claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the

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method claims should be amended during prosecution either to maintain dependency on the method claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

17. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

18. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

19. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback, Ph.D.** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

JML
January 7, 2005

A handwritten signature in cursive script, reading "Janine Spector". The signature is written in black ink and is positioned to the right of the typed name "Janine Spector".